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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,307	01/11/2001	Sam J. Milstein	1946/1A483-US8	8759

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/21/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,307

Applicant(s)

MILSTEIN ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-127 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 38-49 and 75-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-37, 50-74 and 87-127 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Request for extension of time, notice of appeal, request for reconsideration and Terminal disclaimer, all dated 2-12-03 is acknowledged.

In view of the terminal disclaimer filed 2-12-03 and applicant's request for reconsideration, the finality of the rejection of the last Office action is withdrawn.

Upon reconsideration, examiner has further extended the search to other species and sub-species recited in restriction requirement. Accordingly, claims 13-37, 50-74 and 87-127 have been considered for examination.

Claim Rejections - 35 USC § 112

Claim 37 recites the limitation "mimetic" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-16, 18, 23-25, 27, 32, 50-53, 55, 60-62, 64, 69, 87-90, 92, 97-99, 101, 106 and 112-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,873,087 to Morishita et al (Morishita) or US 4,442,090 to Kakeya et al (Kakeya).

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Instant claims recite a composition or a method of preparing a composition comprising a biologically active agent and a complexing perturbant, which has a molecular weight between 150-600 daltons and the perturbant is covalently linked to the active agent in a supramolecular complex formed by exposing the active agent to the perturbant. Instant dependent claims are limited by either a specific perturbant or the specific active agent.

Morishita teaches a preparation containing an absorption promoter and a medically active agent for promoting absorption through a gastrointestinal organ such as colon, rectum or through vagina. The absorption promoter substance of Morishita is an N-acyl amino acid or N-acyl peptide derivative, of formula I (col. 1, lines 5-10, col. 3, lines 13-15) and is obtained by the reaction of an acid (R-COOH) with an amino acid or peptide. The carboxylic acids and amino acids used for preparing N-acyl amino acids are described in col. 4 and 6 and include those described in the instant specification. Among the medically active agent, Morishita describes hormones, such as insulin, antibiotics etc (col. 5, lines 25-68). Morishita fails to specifically teach that the absorption promoter is non-covalently linked to the active agent or the molecular weight of the promoter. However, Morishita teaches the same components of the instant claims and accordingly, the burden is on the applicants to show how the teachings of Morishita differs from the instant. While Morishita does not specifically teach subcutaneous, intranasal or sublingual delivery routes, instant claims recite the delivery route in an intended format i.e., "sublingually deliverable, for intranasal delivery" etc. Accordingly, absent showing evidence to the contrary, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use appropriate amounts of the absorption

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promoting agent for delivery through intranasal or sublingual or any other delivery route because Morishita teaches that N-acyl amino acid or N-acyl peptide absorption promoters markedly increase the absorption of the drug and maintain high concentration of active agent in the blood for a long time.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-37, 50-74 and 87-127 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,071,538. Although the conflicting claims are not identical, they are not patentably distinct from each other because patented claims also recite the same composition as that of the instant claims i.e., a biologically active agent and a perturbant that reversibly transforms the active agent upon non-covalent binding with the active agent and together both the perturbant and the active agent form a supra molecular complex. While the patented claims recite oral delivery and instant claims recite subcutaneous or intranasal or sublingual, the limitations in both the patented claims as

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well as the instant claims suggest a future intended use and accordingly carry no patentable distinction. Thus, the instant composition and the method of preparing the instant composition are anticipated by the patented claims.

Claims 13-37, 50-74 and 87-127 are directed to an invention not patentably distinct from claims 1-20 of commonly assigned US 6,071,538. Specifically, the instant active agent transport systems containing a biologically active agent and a perturbant that reversibly transforms the active agent, forming a non-covalent bonding with active agent is also described in the above patent.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US 6,071,538, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

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Claims 13-37, 50-74 and 87-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,017,538 (hereafter '538).

'538 teaches active agent transport systems containing biologically active agent that can exist in native or denatured or an intermediate conformational state which is exposed to a perturbant that is non-covalently bonded to the active agent. The perturbant reversibly transforms the active agent to form a transportable supra molecular complex, and thus aids in the delivery of biologically active agent. '538 teaches the same classes of perturbants and active agents, which are claimed in the instant invention (see entire document). Further, '538 teach that the transport system is capable of transporting active agents across mucus membranes such as gastro-intestinal mucosa. '538 fail to teach the instant routes of administration. However, instant claims recite various routes of administration in an intended format, which carries no patentable distinction. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the composition of '538 containing an active agent and a perturbant that reversibly transform the active agent so as to enable the active agent to be transported across the mucosal membranes. Accordingly, one of an ordinary skill in the art would have expected to transport the active agents of using the perturbants across other mucosal membranes such as those of nasal tissues or the mouth cavity.

Claims 13-37, 50-74 and 87-127 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,221,367. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the perturbant of the patented claims is a species the generic perturbants claimed in the instant invention.

Minor Informalities

Examiner notes that the word "reversibly" has been misspelled in the instant independent claims. It is suggested to applicants to correct the same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lakshmi S Channavajjala
Examiner
Art Unit 1615
March 18, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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